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JUN 15 2005

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In re Application of	:
Richard A. Earl et al	:
Serial No.: 10/612,014	: PETITION DECISION
Filed: July 3, 2003	:
Attorney Docket No.: 102258.156	:

This is in response to the petition under 37 CFR 1.144, filed March 30, 2005, requesting withdrawal of an improper restriction requirement.

## BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 on July 3, 2003, and contained claims 1-58. In a first Office action, mailed May 27, 2004, the examiner set forth a restriction requirement, as follows:

Group I – Claims 1-5, 51, 55-56 and 58, drawn to compounds of formula I or II and its compositions;

Group II – Claims 6-15, drawn to a method of using the compounds of formula I or II;

Group III – Claims 16-17, 29-39, 57 and 52-54, drawn to a multiple active ingredient composition; and

Group IV – Claims 18-28 and 40-50, drawn to a method of using the multiple active ingredient compounds.

In addition, election of a single species within whichever group was elected was required. The examiner further indicated that upon election of a single species the Office would review the election and determine the scope of compounds to be examined. The examiner also noted that process claims having the same scope as allowable product claims would be rejoined if product claims were elected for prosecution.

Applicants replied on June 17, 2004, electing Group I and the species of Example 20 with traverse, and proposing a modified restriction requirement based on Formula I (Group I) and Formula II (Group II). Applicants argued that this would be less burdensome to the examiner for search and examination.

The examiner mailed a second restriction requirement to applicants on September 3, 2004, in which a 57 way restriction requirement (not reproduced herein) was set forth. The examiner argued that the compounds of Groups 1-27 of Formula I and Groups 27 (sic 28)-35 of Formula II were chemically, physically and patentably distinct; that the inventions of Groups 1-35 and 36-41 were related as product and process of use; and inventions 42 or 49-50 and inventions 43-48 or 51-56 were also related as product and process of use. Election of species was required for certain groups.

Applicants replied on October 27, 2004, electing Group 10 and the species of Example 20, and vigorously traversing the requirement as improper as the compounds of Formula I and the compounds of Formula II are closely related and not patentably distinct.

On December 30, 2004, the examiner mailed an Office action to applicants responding to the traversal, but maintaining the requirement due to the wide disparity among the various groups and limiting the search and examination to only a part of claims 1-4 and 50 (a portion of the elected Group 10). Claims 1-4 were then rejected under 35 U.S.C., first paragraph as lacking written description, and under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 50 was objected to as depending from a rejected claim.

Applicants replied to the Office action on March 30, 2005, by making a minor amendment to the specification, and amending claims 1, 3 and 55, and responding to the rejections. This petition was filed concurrently.

## DISCUSSION

A review of applicants' claims shows that they are directed first to compounds and/or compositions relating to Formula I or Formula II or kit containing the compound/composition. Second, they are directed to the combination of the compounds of Formula I or Formula II combined with another active ingredient. Lastly, the claims are directed to treating numerous diseases or conditions, both related and unrelated, with the compounds/compositions.

A review of Formula I shows that the compound is  $R_n-C(H)(R_m)-C(=O)-X$ , where  $R_m$  is H or a lower alkyl group.  $R_n$  is defined as 51 different and mostly unrelated ring structures, both carbocyclic and heterocyclic, fused and non-fused. X is defined as 44 different chains having as many as 4 variables and bonded to the  $C(=O)$  atom through O, S or N (a total of 79 different bonded chain structures), many having a ring embedded in the chain which may be carbocyclic, heterocyclic, alkyl or aryl. Thus the only structure common to all compounds of Formula I is the  $C(H)(R_m)-C(=O)$  structure. Such cannot be considered a significant structure for the multitude of compounds encompassed by the formula nor has it been shown that the compound's activity is directly related to this structure. Formula II is similar in that only a " $C(=O)$ " forms the structure common to all structures (the  $CHR_m$  portion of Formula I is eliminated). It is also noted that applicants' claim 1 contains at least 82 specific compounds (identified by ACS Registry number only) or groups of compounds for Formula I which are excluded and at least 56 specific compounds (also identified by ACS Registry number) which are specifically excluded for Formula II. This exclusionary language muddies the scope of the Markush group set forth

leaving the examiner little choice but to carve the improper Markush Group into understandable and recognizable groups based, in this instance, on the various  $R_n$  ring structures which do provide a large number common structures each forming an individual Markush group.

A proper Markush group is formed when a group of compounds (or compositions) has a significant portion of their structure in common and the activity or property claimed is directly related to that structure. For instance, steroids have a large portion of their structure in common (usually 4 or 5 fused rings) and the only difference is in the radicals attached thereto. However the primary activity of steroid compounds is based on or linked to the fused ring structure with the radicals only modifying that activity.

The examiner's initial restriction requirement between Formula I and Formula II compounds and the methods related thereto was not improper and generally agreed to by applicants in their first reply and election wherein they suggested that the method and compound claims should be rejoined and examined together. Upon further consideration the examiner determined that Formula I and Formula II related to so many different basic compounds that further restriction was warranted. Thus the examiner's dividing claim 1 into 27 groups based on the various ring structure for  $R_n$  of Formula I and 8 Groups for Formula II based on  $R_k$  ring structures with Groups 36-57 (later reduced to 56) directed to methods and compositions containing additional active ingredients is not unreasonable. The only error made by the examiner is in stating that upon election of a single species within the Group elected the scope of applicants' invention would be determined. Such is not permitted. Once a Group is elected and a species identified from which examination may begin, if no prior art is found upon which the elected species may be held unpatentable, the examiner must follow M.P.E.P. 803.02 and expand the search and examination to additional species until a reasonable number have been considered. Should no prior art be found on any of the additional species, the entire Group would be considered to avoid the prior art and the claims of the elected Group would be further examined to determine compliance with respect to all other aspects of the statute .

Applicants' arguments are directed to showing that all of the compounds of Formula I are related by stating that all are "nitrosated non-steroidal anti-inflammatory compounds". However, the common structure noted above does not contain a nitroso radical. The nitroso portion is located on the  $R_n$  portion of the compounds which can be markedly different. Applicants further argue that the examiner must show different classifications for the identified groups, different fields of search or separate status in the art. As shown in the second restriction requirement, the various groups are classified properly in several different classes and various subclasses within each class. The various classifications are indicative of a widely divergent search for the compounds as well as showing that they are not closely related.

Also noted (and requested by applicants) by the examiner is that method claims of the same scope as an allowable compound/composition claim (Group elected) will be rejoined upon a finding of allowability of the compound/composition claim and they will then be fully examined for compliance with all other applicable portions of the statute. Such could also be extended to those claims containing additional active ingredients.

## DECISION

The petition is **DENIED** except that the examiner will follow the guidelines of M.P.E.P. 803.02 in conjunction with the election of species search and examination practice.

**The application will be forwarded to the examiner for further consideration not inconsistent with this decision.**

Should there be any questions about this decision please contact William R. Dixon, Jr., by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.



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